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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,367	11/30/2005	Derek Woolfson	000487-00037	3383

22907 7590 02/06/2007  
BANNER & WITCOFF  
1001 G STREET N W  
SUITE 1100  
WASHINGTON, DC 20001

EXAMINER
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KHANNA, HEMANT

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/526,367

Applicant(s)

WOOLFSON ET AL.

Examiner

Hemant Khanna

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 16-32 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/30/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election with traverse of claims 1-15 that belong to Group I in the reply filed on December 01, 2006 is acknowledged. The traversal is on the ground(s) that the Hartgerink reference does not teach or disclose the claimed limitation "a fiber-shaping peptide" (Response, third paragraph, page 1). Further, the Applicants argue that the presence of the above-mentioned utility in the claimed peptide renders the invention a common inventive concept (Response, third paragraph, page 1).

The applicant's arguments are not found persuasive. The expression "special technical feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole makes over the prior art. Thus, the recitation of a common property without the recitation of a significant structural element cannot be considered to be a special technical feature. Groups I-V are drawn to fiber-shaping peptides, self-assembling peptides and protein structures represented by sequences that do not share a significant structural element that is essential to the common property of being fiber-shaping peptides.

MPEP 2112 reads "The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable". Something which is old does not become patentable upon the discovery of a new property, use, or application. Even if the Applicant has discovered a new property (fiber-shaping peptides), such a discovery does not render the peptides itself new in the art. As such, since the scope of the peptides encompassed by Groups I-V is extremely broad, they cannot be considered a special technical feature.

The restriction between Groups I-V is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's elected the species of SEQ ID NO:3 represented by the sequence (NH<sub>3</sub>-KIRRLKQKNARLK(βA)<sub>3</sub>)<sub>2</sub>-K. The Examiner has considered this request, and is willing to search and examine the generic invention of Group I, but only in so far as being drawn to the elected species, namely a fibre-shaping peptide comprising "a hub and a plurality of peptide monomer units consisting of SEQ ID NO:3"

Claims 1-32, and 36 are pending. Claims 16-32, and 36 are withdrawn from consideration as being drawn to a non-elected invention. Election was made **with** traverse in the reply filed on December 01, 2006.

### ***Specification***

2. The disclosure is objected to because of the following informalities: the absence of SEQ ID NO:'s after all amino acid sequences is inconsistent with the disclosure rules. See 37 CFR 1.821 (d). Such sequences are present on page 6, and 8 of the specification. Appropriate correction is required.
3. The disclosure is objected to because of the following informalities: reference to the drawings in the heading "Brief Description of the Drawings" in the accompanying disclosure is lacking. See 37 CFR 1.74. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, claims 1-15 recite a fibre-shaping peptide by name only. The specification defines a fiber-shaping peptide as one comprising a hub and a plurality of peptide monomer units, wherein the fiber-shaping peptide is between 15 and 100 amino acids in length and wherein the peptide monomer units are capable of binding to self-assembling peptides. Therefore, no structural limitations are present in claim 1. Claims 2-15 depend from claim 1 in part, and thus also encompass fibre-shaping peptides having no structural limitations. For each of these claims, there is no identification of any particular portion of the structure or sequence that must be conserved. The specification discloses two sequences that

are capable of interacting with self-assembling peptides: the sequences of SEQ ID NO: 3 and SEQ ID NO:5. These two closely related species are not representative of the structurally undefined genus recited in the claims. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With the exception of SEQ ID NO: 3 and SEQ ID NO:5, the skilled artisan cannot envision the detailed chemical structure of the encompassed fiber-shaping polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to

be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the the sequences of SEQ ID NO:3 and SEQ ID NO: 5, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

### ***Conclusion***

6. The Applicants species of  $(\text{NH}_3\text{-KIRRLKQKNARLK}(\beta\text{A})_3)_2\text{-K}$  is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.


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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Hemant Khanna Ph.D.  
January 26, 2006



B. DELL CHISM  
PRIMARY EXAMINER